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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,606	05/08/2001	Rubinah K. Chowdhary	273012011700	4962
25225	7590	10/16/2006	EXAMINER	
MORRISON & FOERSTER LLP 12531 HIGH BLUFF DRIVE SUITE 100 SAN DIEGO, CA 92130-2040			KISHORE, GOLLAMUDI S	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/851,606

Applicant(s)

CHOWDHARY ET AL.

Examiner

Gollamudi S. Kishore, Ph.D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23, 26-28 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23, 26-28 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The RCE dated 7-27-06 is acknowledged.

Claims included in the prosecution are 1-23, 26-28 and 30.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-23, 26-28 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 4 recite, "upon hydration with an aqueous medium, said complex is" and then recite as Markush members, 'micelles, vesicles, emulsion, gel and matrix. It is unclear as to how just a Hydration of the powder would result in different products claimed. One can understand hydration resulting one specific product. Steps leading to the formation of different products are missing in the claim.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that it is known in the art that the nature of the hydration product formed is affected by the nature of the poloxamer carrier agent and that as described in the specification, poloxamers may be emulsion forming, micelle forming and water soluble which form an extended network in solution. This argument is not persuasive since instant claims also recite vesicles and specification does not show how a vesicle is formed. Specification also does not provide the distinction between the

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terms, 'gel' and 'network'. In view of the terminal disclaimer, the double patenting rejection is withdrawn.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-23, 26-28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider (6,258,378) by itself or in combination with Lyons (5,616,342) and Young (6,375,930).

Schneider discloses formulations containing liposomes and an active agent (diagnostic and therapeutic agents) in combination with polymers such as Pluronic F-108 and poloxamer. The method of preparation involves mixing the active agent with the emulsifying agent, poloxamer or Pluronic F-108 and the phospholipids such that the emulsifying agent is inside and outside the liposomes. The compositions are in a dried form and contain cryoprotectant such as sucrose (endo and exo-support) (abstract, col. 2, line 50 through col. 6, line 7, col. 7, lines 1-4 and 51-56, Examples and claims). What is lacking in Schneider is the teaching that the therapeutic agent or the diagnostic agent be a photosensitizer. However, it would have been obvious to one of ordinary skill in the art to encapsulate any active agent including a photosensitizer, with a reasonable

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expectation of success since Schneider teaches general applicability of the system to any agent and provides guidance to one of ordinary skill in the art.

Lyons discloses emulsion formulations containing photosensitizers such as claimed texaphyrins and sapphyrins and block copolymers such as poloxamers (abstract, col. 3, line 10 through col. 8, line 22 and claims).

Young discloses that photodynamic therapy could be practiced with photosensitizing material in carriers such as micelles and liposomes (abstract, col. 11, line 33 through col. 13, line 43).

One of ordinary skill in the art would be further motivated to use Schneider's composition to deliver a photosensitizer since the references of Lyons, and Young show the routine practice in the art of the use of poloxamers containing emulsion systems, micelles and liposomes for the delivery of photosensitizers.

Note: The methodology used by Schneider in 6,258,378 for preparing the dried powder in the presence of sucrose is disclosed in Schneider (4,29, 360), which has been cited of interest before (note abstract, col. 2, line 18).

4. Claims 1-23, 26-28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lyons (5,616,342) in combination with Klaveness (5,674,468), See (6,015,576) individually or in combination.

Lyons as pointed out above, discloses emulsion formulations containing photosensitizers and poloxamer or Pluronic F 127 (abstract, col. 4, lines 44-65 and Example 1). What is lacking in McCarty is the teaching of the preparation of the composition in a dried form in the presence of solid supports such as lactose.

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Klaveness while disclosing emulsion formulations containing Pluronics teaches that the emulsions can be lyophilized in the presence of lactose to prepare dried forms (col. 40, lines 28-45).

See teaches that emulsions can be lyophilized in the presence of cryopreservatives such as lactose to stabilize the emulsions and the contents (abstract, col. 6, line 57 through col. 7, line 8).

To prepare the emulsion of Lyons in a dry form using lactose as the solid support would have been obvious to one of ordinary skill in the art since such a procedure would stabilize the composition as taught by Kloveness, and See.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that there is no motivation to combine the references, which are non-analogous art (Page 8 of the response). The examiner disagrees since all the three references pertain to emulsions and liposomes which are micelles or emulsions in a continuous medium and therefore, analogous art and not non-analogous. Applicant's arguments that Lyons does not teach the preparation of the composition in a dried form. The examiner agrees, but points out that both Kloveness and See teach the knowledge in the art of preparing the dried forms of the compositions using cryopreservatives such as disaccharides. In this context, the examiner regrets the error of using the word, McCarty; but the intent is clear that it refers to Lyons. Applicant's arguments that Lyons reference does not teach the use of various copolymers as carriers which themselves will emulsify upon hydration are not persuasive as discussed above.

Applicant's arguments that Klaveness teaches naphthalene emulsions are not persuasive since Klaveness is combined for its teachings of lyophilization of emulsions in the presence of sugars and one would expect similar lyophilization results, irrespective of the components and applicant has not shown that to be otherwise. Applicant's arguments that See teaches lyophilization of an emulsion comprising liposomal antigen, but silent regarding photosensitizers and a triblock copolymer. This argument is not persuasive since the rejection is made on the combination of the references and not just See alone.

6. Claims 1--23, 26-28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lyons (5,616,342) in view of either Desai (6,074,666) or Madden (5,389,378) in further combination with Unger (6,028,066).

The teachings of Lyons have been discussed above. What are lacking in Lyons are the teachings of the preparation of the composition in a dried form in the presence of solid supports such as lactose and the use of claimed photosensitizers.

Desai discloses a method of preparation of lyophilized powders containing a phospholipid, a benzoporphyrins and lactose (endosupport) for photodynamic therapy (note columns 6-7, Examples and claims, claim 8 in particular).

Madden discloses a method of preparation of lyophilized powders containing a phospholipid, a benzoporphyrin and lactose (endosupport) for photodynamic therapy (note Examples). The formulations are enclosed in a capsule (exo-support).

Unger while disclosing the formulations containing liposomes and micelles for therapeutic and diagnostic purposes teaches that lyophilized compositions have

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advantage of greater shelf life and to prevent the agglutination as a result of lyophilization, additives such as glucose and trehalose are added (note the abstract, col. 4, lines 9-58 and col. 79, lines 45-57).

To include sugars such as lactose and trehalose and lyophilize the preparations of Lyons would have been obvious to one of ordinary skill in the art because Unger teaches that lyophilized compositions have advantage of greater shelf life and to prevent the agglutination as a result of lyophilization, additives such as glucose and trehalose and polymers such as PEG and polyvinyl pyrrolidone are added; the inclusion of sugars would have also have been obvious to one of ordinary skill in the art since these are protective agents according to Madden and these are routinely added in freeze dried preparations containing photosensitizers according to Desai.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's only argument is that the claims now recite specific poloxamers and the references are silent regarding the recited poloxamers. This argument is not persuasive since although Schneider exemplifies with Pluronic F-108 (examples 1 and 6), on column 7, lines 1-3 and col. 13, line 11 he clearly states that Pluronic and Poloxamer surfactants could be used. Therefore, it would have been obvious to one of ordinary skill in the art to select the appropriate poloxamer. Furthermore, Lyons uses Pluronic F-127, which according to the table on page 48 of the specification is the same as poloxamer 407 which applicants claim.

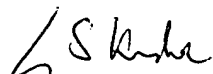
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is

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(571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Gollamudi S Kishore, Ph.D
Primary Examiner
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GSK